IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MYLAN PHARMACEUTICALS, INC.	:	**Civil Action No. 2:21-cv-13087 (JXN/JSA)**
Plaintiff,	:	
	:	Hon. Julien Xavier Neals
v.	:	Hon. Jessica S. Allen
	:	
TEVA PHARMACEUTICALS INDUSTRIES LTD., TEVA PHARMACEUTICALS USA, INC., TEVA NEUROSCIENCE, INC., and TEVA SALES & MARKETING, INC.,	:	JOINT DISCOVERY PLAN
Defendants.	:	

JOINT DISCOVERY PLAN

1. Factual Description of the Case

(a) Plaintiff's Description of the Case

Plaintiff Mylan Pharmaceuticals, Inc. ("Mylan") sues defendants Teva Pharmaceuticals Industries Ltd., Teva Pharmaceuticals USA, Inc., Teva Neuroscience, Inc., and Teva Sales & Marketing, Inc. (collectively, "Teva") for violations of federal and state antitrust law, Lanham Act, and violations of New Jersey state and common law. Teva has unlawfully maintained a monopoly over its most profitable product—Copaxone—by delaying Mylan's lower-priced generic competition (generic "glatiramer acetate" or "GA") from entering the market and diminishing uptake upon entry. Teva has also violated the Lanham Act through the dissemination of falsehoods about Mylan's GA including, but not limited to, the efficacy of Mylan's product, the nature of Mylan's GA, and the accessibility and prevalence of Mylan's patient support services. Teva has also tortiously interfered with Mylan's prospective contractual relations, and engaged in Trade Libel and Unfair Competition. Teva's actions also are the subject of ongoing lawsuits and government investigations.

Copaxone treats patients with relapsing forms of Multiple Sclerosis ("MS"). Copaxone is indicated as a disease-modifying therapy for the treatment of patients with relapsing forms of MS, including the reduction of the frequency of relapses in relapsing-remitting MS ("RRMS"). RRMS is manifested by relapses and slow progress of the disease that can affect the functioning of multiple systems. The majority of MS patients have RRMS. Disease-modifying therapies alter the course of the disease and prevent flare-ups.

Mylan filed ANDAs for the 20mg version of Copaxone in June 2009 and for the 40mg version in February 2014, and developed extensive support services including a website and a patient hub. FDA approval did not come until October 2017, because Teva delayed generic approval of Mylan's GA with an incessant campaign of baseless litigation, including patent litigation, and serial abuses of the Citizen Petition regulatory process. FDA approval would have come earlier if not for Teva's efforts to delay Mylan's entry.

Upon receiving FDA approval, Mylan immediately marketed its therapeutically equivalent GA product, but once again Teva employed exclusionary measures to maintain its monopoly over Copaxone. Teva forestalled Mylan from competing by spreading uncorrectable falsehoods to doctors and patients regarding the effectiveness of Mylan's product and Mylan's support to patients; implementing economically irrational pricing; combining illegal rebating with coercion of specialty pharmacies to prevent the dispensing of Mylan's product; filing a baseless lawsuit against the FDA to reclassify Copaxone as a biologic expressly to avoid substitution at the pharmacy; and even paying illegal kickbacks, resulting in the DOJ suing Teva.

Teva illegally maintained a monopoly over Copaxone through its exclusionary tactics and diminished generic uptake. During this period of time, Teva faced no competitive pressure and freely raised prices—from an annual price of $8,292 in 1996 to $91,401 in 2017. The robustness of Teva's scheme was further revealed in 2020 when the U.S. House of

Representatives Committee on Oversight and Reform released a report, supported by dozens of internal Teva documents, detailing Teva's unlawful Copaxone conduct.

Mylan filed its Complaint on June 29, 2021, and Teva moved to dismiss Mylan's Complaint on November 19, 2021. Mylan's opposition to Teva's motion to dismiss was served on January 31, 2022, and Teva's reply is due on March 21, 2022.

For purposes of this document, Teva's entities are considered one party. "Parties" refers to Plaintiff and Defendants.

(b) Defendants' Description of the Case

Teva has sold its Copaxone product in the United States since 1997. Copaxone has been extremely well received and is widely prescribed for the treatment of multiple sclerosis, though it has always faced significant competition as it is only one of several products indicated for that use. The active ingredient in Copaxone (glatiramer acetate, or "GA") is an extraordinarily complex product, and it is sold in liquid form that a patient self-administers using an auto-injector. Copaxone originally was available only in a 20 mg dose, requiring daily administration. In 2014, Teva increased its offerings by adding a 40 mg dose, which a patient needed to inject only three times per week. Not surprisingly, the new dose proved extremely popular, though some patients and their physicians elected to remain on the 20 mg form.

Mylan is a competitor of Teva that started selling a generic version of Copaxone in 2017, in both doses. Another competitor in this space, Sandoz, beat Mylan to market by more than two years, launching its generic 20 mg product in 2015. Mylan is apparently dissatisfied with the profits it has been able to achieve since its 2017 launch, and it has chosen to blame Teva by filing this lawsuit. Mylan accuses Teva of violating the Sherman Act, the Lanham Act, and various New Jersey laws by allegedly stifling generic competition

to Copaxone and harming Mylan. Teva has filed a motion to dismiss Mylan's claims in their entirety (the "Motion"), and briefing will be completed by March 21, 2022.

Mylan's allegations boil down to two arguments, each of which fails. First, Mylan alleges that Teva improperly *delayed* Mylan's ability to obtain FDA approval and start selling its generic GA products. This claim suffers from numerous failings: among other flaws, the claim is time-barred, and it challenges constitutionally protected conduct (filing suit to protect Teva's patent rights and petitioning the FDA) that is immune from liability under the *Noerr-Pennington* doctrine. But most fundamentally, Mylan's "delay" theory suffers from an obvious and insurmountable causation problem. Mylan premises its theory of delay on actions taken by Teva long before FDA's approval decision, and the *exact same* challenged conduct did not prevent FDA from approving Sandoz's ANDA two years earlier in 2015. Mylan simply has no explanation for how Teva's conduct – rather than its own regulatory difficulties in manufacturing and securing approval of an exceptionally complex drug product – somehow delayed Mylan's market entry until 2017 when Sandoz was able to launch in 2015. Notably, elimination of Mylan's baseless "delay" claim would, on its own, substantially streamline the litigation by eliminating whole categories of discovery, including any discovery related to Teva's conduct prior to Mylan's approval in October 2017.

Second, Mylan argues that Teva improperly *impeded* Mylan's ability to compete after Mylan entered the market in 2017. Mylan's allegations cover a litany of competitive practices: Teva's contracting strategies with payors (and the inclusion of significant rebates); Teva's charitable contributions to third-party foundations, which Mylan alleges functioned like co-pay support payments to Medicare patients; and marketing campaigns intended to persuade doctors to continue prescribing Copaxone rather than generic alternatives. Despite Mylan's conclusory labels, its claims attack legitimate forms of competition. At bottom, Mylan seems to argue that Teva was required to cede the field once generics became

available, and that Teva acted improperly by competing with the generics, including through substantial price discounting. But no law prevents a company – even a purported monopolist, which the evidence will show Teva is not – from engaging in legitimate competition and price discounting. And *consumers* benefitted from Teva's vigorous price competition, even if *Mylan* itself lost sales as a result.

Mylan tries to discount this price competition by relying on the *list* price for Copaxone while ignoring the *net* prices, which factor in those price concessions. In testimony to Congress, Mylan's own CEO described a focus on list prices as misleading in this industry because it obscures the true price at which a product is sold. Mylan's decision to nonetheless feature list prices here simply reveals the weakness of its case. Ultimately, Mylan's claims reduce to a grievance about losses sustained through Teva's legitimate efforts to compete. Those allegations cannot support a claim for the violation of the antitrust law, or any other claim that Mylan has put forward. If the Court agrees with Teva on this point (in addition to the argument regarding "delay" above), the Complaint should be dismissed in its entirety.

Seeking to paper over the weaknesses in its claims, Mylan has tried to create an appearance of impropriety by referencing a 2020 report by a subcommittee of the U.S. House of Representatives that investigated pricing practices related to Copaxone, along with several other leading brand drugs. But the House subcommittee is not an antitrust tribunal. And contrary to Mylan's insinuations, the subcommittee did not purport to find that Teva had violated any law. Indeed, the subcommittee's mandate did not target competition issues, but rather focused on possible legislative reforms to lower drug prices—principally, the question of whether the government should have the power to negotiate prescription drug prices with manufacturers. Similarly, Mylan also tries to cast aspersions on Teva's conduct by referencing certain "ongoing lawsuits and government investigations" about Copaxone. But

no Court has found Teva to have violated *any* U.S. law in relation to Copaxone sales in the United States. Moreover, Mylan's effort to leverage other lawsuits does nothing to bolster its claims. For example, Mylan notes that Teva and the United States are currently in litigation regarding the government's allegations that Teva's charitable contributions to third-party foundations resulted in violations of the Anti-Kickback Statute by subsidizing Copaxone purchases by Medicare patients. Teva vigorously disputes those allegations. But regardless, Mylan has no standing to bring an AKS claim, and no basis to complain about conduct that—*according to Mylan's own theory*—made Copaxone more attractive to patients by lowering their out-of-pocket cost.

For all of the reasons set forth above, Teva believes this case should be resolved on its Motion. But if the case does proceed to discovery, Teva expects that the evidence will show that Mylan's disappointing sales figures are attributable, at least in significant part, to market dynamics that are independent of any of Teva's challenged conduct. In particular, numerous institutional features of the pharmaceutical marketplace caused consumers at various levels of the market to prefer Copaxone over generic alternatives. For example, industry commentators have noted that Mylan likely mispriced its generic GA product in ways that made it less attractive to purchasers. Likewise, a recent minority report from the same House subcommittee on which Mylan relies explained how the business model of Pharmacy Benefit Managers ("PBMs"), who operate as critical middlemen in the pharmaceutical marketplace, can make brand drugs more attractive to them than generics. Teva should not be found liable because customers prefer its pricing model to Mylan's. In addition, many patients apparently have had negative experiences using a generic GA product. An FDA official recently disclosed that the agency is investigating reports of injector failures and bent needles associated with generic GA products—reports that increased markedly starting in 2018, shortly after Mylan's approval. Such negative experiences can be expected to reduce

doctors' and patients' willingness to use a generic in place of the brand Copaxone to which they were accustomed, causing Mylan's sales to be lower than it had expected for reasons that have nothing to do with Teva. If this case proceeds past the motion to dismiss stage, all of these and other issues will need to be investigated through expensive and time-consuming discovery. But such discovery would be avoided if the Court grants Teva's pending Motion.

Lastly, a comment is required about the proper scope of this case. Even though Mylan's Complaint explicitly states that it is based on alleged harms to competition in the United States, the Complaint contains numerous references to alleged conduct outside the United States which has no conceivable impact on U.S. competition. Teva has moved to strike those portions of the Complaint. But regardless of whether the Court grants that request, or allows those allegations to remain in the Complaint merely "for context," as Mylan has since argued in defense of its pleading, Teva objects to any discovery into its foreign conduct, which would be unduly burdensome.

2. Settlement Discussions

The Parties have not yet engaged in substantive settlement discussions.

3. Initial Disclosures

Mylan served its information required by Fed. R. Civ. P. 26(a)(1) on February 8, 2022. Teva respectfully requests leave to serve its initial disclosures on March 4, 2022, in light of unforeseen family circumstances that prevent Teva from serving disclosures by the February 22, 2022 deadline under Fed. R. Civ. P. 26(a)(1). Mylan does not object to Teva's request for an extension.

4. Describe any discovery conducted other than the above disclosures.

No discovery has occurred aside from Mylan's disclosure of information required by Fed. R. Civ. P. 26(a)(1). Mylan served requests for production of documents on October 5,

2021. Absent a deferral of discovery, Teva's response to those requests are currently due on March 10, 2022.

5. Motions Prior to Completion of Discovery

This is premature and should be determined after the pending motion to dismiss is resolved. As detailed below, Teva seeks to defer discovery pending the resolution of its Motion. To the extent the Court may prefer briefing on the issue, Teva would request a briefing schedule to do so.

6. Discovery

(a) Discovery is needed on the following subjects, including but not limited to:

(1) Plaintiff's Position

Mylan expects to require fact and/or expert discovery on all issues raised in the Complaint, Teva's Motion to Dismiss, Mylan's Opposition to Teva's Motion to Dismiss, and any Answer and/or Counterclaims, including but not limited to:

- Copaxone, Glatiramer Acetate, Glatopa, and other generic forms of Copaxone ("Relevant Products")
- Research and development of Relevant Products
- FDA approval of Relevant Products
- Teva's Citizen Petitions to the FDA regarding Relevant Products
- Correspondence between Teva and the FDA or other governmental bodies regarding Relevant Products, anything produced to the governmental bodies, and all internal discussions of the same, including Citizen Petitions and patent litigation regarding the Relevant Products
- Marketing and promotion of Relevant Products
- Teva's marketing statements about the Relevant Products, including misstatements about Mylan's support services and the efficacy, availability, and safety profile of generic GA

- Economic and marketing information regarding Relevant Products, such as market-share, revenue and sales, and/or profit projections
- Efforts to convince doctors to prescribe and patients to request Copaxone instead of the Relevant Products
- Physicians paid by Teva who disseminated falsehoods about the Relevant Products and/or generated concern regarding the Relevant Products
- Effects of generic entry
- Teva's "generic defense" strategy
- Teva's planning documents for the Relevant Products and generic entry
- Teva's payments to third parties, including The Assistance Fund and Chronic Disease Fund, related to copayment support
- Agreements, negotiations, and decisions between Teva and third parties regarding Relevant Products
- Teva's communications and contracting practices with PBMs, specialty pharmacies, third-party payers, and other healthcare entities related to the Relevant Products, including rebates, exclusivity, and other payments
- Any FTC investigation or investigation by any other agency, including state Attorneys General offices, and the Department of Justice, into Teva's conduct as it relates to Relevant Products
- Congressional inquiry into Copaxone
- Other litigations in which Teva has participated, involving similar or identical facts
- Other litigations in which Teva has participated, involving Copaxone
- Teva's patent litigations regarding Copaxone, including litigation in the US, Ireland, rest of Europe, and India
- Teva's Board of Directors materials and other information provided to executives pertaining to Copaxone

The foregoing list is not exhaustive and without prejudice to Mylan's right to designate additional topics for discovery, which is expressly reserved.

(2) Defendant's Position

The scope of discovery is dependent on the outcome of Teva's pending Motion. Even if Teva's Motion is granted only in part, the scope of discovery may be substantially narrowed both with respect to the factual issues to be addressed as well as the relevant time period. As a result, Teva cannot detail what discovery may be needed into Teva's own practices following a ruling on its Motion. Teva respectfully submits that discovery should be deferred pending the resolution of that Motion, as set forth in more detail below. *See* Section 6(b)(2).

Nevertheless, if Teva's Motion is not granted in full, Teva anticipates discovery will be needed on the following subjects, at a minimum:

- Copaxone, GA, Glatopa, and other generic forms of Copaxone
- The relevant market in which Copaxone and generic GA products compete, including the parties' assessment of the competitive landscape
- Research and development of Copaxone, GA, Glatopa, and other generic forms of Copaxone, including the FDA approval process and any challenges to the same
- Correspondence with the FDA or other governmental bodies regarding generic Copaxone, including but not limited documents concerning the timing of approval for Mylan's generic GA products
- The effects, or lack thereof, of any litigation filed by Teva in delaying FDA's approval of Mylan's ANDA for generic GA products
- The effects, or lack therefore, of any citizen petition submitted by Teva in delaying FDA's approval of Mylan's ANDA for generic GA products
- Pricing, rebating, marketing and promotion of Copaxone, GA, Glatopa, and other generic forms of Copaxone, as well as other products in the relevant market
- Agreements with Pharmacy Benefit Managers and payors, and the negotiations of the same
- Actual and forecasted sales of Copaxone, GA, Glatopa, and other generic forms of Copaxone
- Institutional dynamics in the healthcare marketplace that made Teva's Copaxone more attractive to purchasers than generic GA products

- Complaints or concerns about Mylan's GA product for any reason, including efficacy, side effects, difficulty with operation of auto-injectors, auto-injector failures, needle problems, adverse event reporting, and pharmacovigilance issues, among others

- Patient assistance programs offered for Copaxone, GA, Glatopa, and other generic forms of Copaxone and any patient assistance programs Mylan or Viatris has offered for any of its programs, including copay coupons, copay cards, or any other program

- Mylan's or Viatris's effort to encourage doctors to prescribe products with "Dispense as Written" instructions for generic GA and any other products

- Teva's allegedly false statements about Mylan's GA product and services, including any evidence of such statements and analysis of any effect of such statements, and Mylan's actions in response thereto

This list is not exhaustive and Teva reserves the right to supplement or modify this list in any way in response to the Court's ruling on Teva's Motion or otherwise.

In addition, Mylan has identified certain issues in discovery that are not relevant and should not be permitted regardless of the outcome on Teva's Motion. Among other topics, Teva's conduct outside of the United States, including litigation surrounding Copaxone and any foreign marketing and sales of Copaxone, has no bearing on the issues in this case. Similarly, Mylan has requested the reproduction of various materials made available and produced in unrelated investigations and litigations. Such cloned discovery is inappropriate and should not be permitted here, as addressed below.

(b) Discovery will be conducted as follows:

(1) Plaintiff's Position

Mylan proposes that discovery should proceed in two phases. Mylan proposes that the following categories of documents, which are immediately accessible and capable of production without further collection and review, and which may help to focus other discovery efforts, will be produced on an expedited basis, on the terms discussed below ("Phase 1"). Such documents have been previously produced and will require minimal effort to re-produce in this case.

A. Phase 1 Production by Defendants

Mylan served Teva with Mylan's first set of its Requests for Production ("RFPs") on October 5, 2021 pursuant to Fed. R. Civ. P. 26(d)(2) and 34 and Local Civil Rule 34.1, seeking easily accessible documents previously produced by Teva. Teva objected to these requests as premature and has not produced documents falling within the scope of Mylan's first set of RFPs. The items below include materials requested by Mylan's first set of RFPs.

Materials Produced to Congress: All non-privileged materials submitted to the Congress, in response to subpoenas or voluntarily, as part of the Congressional investigations into Teva's conduct as it relates to Copaxone. Any transcripts or records of depositions, interviews, or other testimony produced or provided as part of this investigation should also be produced.

Materials Produced to the Department of Justice: All non-privileged materials submitted to the Department of Justice, in response to requests or voluntarily, as part of any investigation into Teva's conduct as it relates to Copaxone.

Materials Produced to the Food and Drug Administration: All non-privileged materials produced to the Food and Drug Administration, either by request or voluntarily, in connection with Teva's Citizen Petitions in connection with Copaxone.

B. Phase 1 Production by Mylan

Materials Produced to the FDA: All non-privileged documents provided to the FDA regarding Mylan's generic GA.

C. Timing of Phase Productions

Parties will produce materials on a rolling basis, and will have substantially completed production of the Phase 1 materials by April 22, 2022.

In Phase 2, Mylan proposes that all remaining discovery will proceed according to the case schedule below. That schedule provides for, among other things, the substantial

completion of the production of documents responsive to all requests for production served on or before April 22, 2022 by no later than September 23, 2022.

Mylan submits that the Court should adopt the schedule set forth below for the timing of both Phase 1 and Phase 2 document productions. Subject to any obligation of the parties to supplement discovery under the Federal Rules or the Rules of this Court, any documents produced by a party after the respective foregoing scheduled dates applicable to those documents (a) must not exceed an unsubstantial number of documents (i.e., no more than ten (10) percent), and (b) could not otherwise have been discovered or produced earlier in this case, as demonstrated to the Court by the producing party upon an objection to such production submitted to the Court by the non-producing party. The producing party shall not be permitted to use or otherwise rely upon for any purpose whatsoever in this case any documents sought to be produced after the respective foregoing scheduled dates applicable to those documents that exceed an insubstantial number of documents, absent a showing to the Court of good cause for such belated production and lack of prejudice to adverse parties. The non-producing party shall have the right to use and is not precluded from using such documents for any purpose. This standard is without prejudice to the non-producing party's ability to request different and/or additional relief based upon such conduct by the producing party.

(2) Defendants' Position

Teva maintains that discovery should be deferred pending the resolution of the Motion, as set forth below. In addition, Plaintiff's proposal to phase discovery ignores the significant burden to review and produce irrelevant and potentially irrelevant materials before Teva's Motion is decided.

A. Discovery Should Be Deferred Pending Teva's Motion

Teva maintains that discovery should be deferred until the Court rules on Teva's pending Motion. The Motion includes arguments that, if accepted by the Court, will dispose of Mylan's Complaint in its entirety or in part, with the potential to significantly narrow the issues in the case. These are exactly the circumstances in which deferring discovery is appropriate. *Ghaffari v. Wells Fargo Bank NA*, 621 F. App'x 121, 124 (3d Cir. 2015) (Motions to dismiss under Rule 12(b)(6) "should typically 'be resolved before discovery begins.'" (quoting *Chudasama v. Mazda Motor Corp.*, 123 F.3d 1353, 1367 (11th Cir. 1997)). Teva's Motion will be fully briefed by March 21, 2022, pursuant to a schedule agreed to by the parties and accepted by the Court.

Because antitrust discovery is extremely expensive and burdensome, Teva respectfully submits that substantive discovery should occur after (and only if) the Court determines that Mylan has stated a legally valid claim. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558 (2007) ("The costs of modern antitrust litigation and the increasing caseload of the federal courts counsels against sending the parties into discovery where there is no reasonable likelihood that the plaintiffs can construct a claim from the events related in the complaint.") (citations, quotations, and alterations omitted). Courts in this District consider the following factors to determine whether to defer discovery pending the resolution of a motion to dismiss: (1) whether a stay "would unduly prejudice or present a clear tactical disadvantage to the non-moving party"; (2) "whether the denial of the stay would create a clear case of hardship or inequity for the moving party"; (3) "whether a stay would simplify the issues and the trial of the case"; and (4) "whether discovery is complete and/or a trial date has been set." *Actelion Pharm. Ltd. v. Apotex Inc.*, No. 12-5743, 2013 WL 5524078, at *3 (D. N.J. Sept. 6, 2013) (internal citations omitted). Every factor weighs in favor of a stay here.

First, Mylan would not be unduly prejudiced or tactically disadvantaged if discovery were deferred until Teva's Motion is resolved. Teva has complied with its discovery obligations to take reasonable steps to preserve relevant materials based on the allegations in the Complaint and has issued the appropriate legal holds for that information. Second, requiring discovery to proceed absent a ruling on the Motion would require Teva to incur substantial costs and expenses associated with collection and review of broad categories of data and documents which may have no bearing on the litigation once Teva's Motion is resolved. Third, even if Teva's Motion is not granted in full, it may still significantly narrow the issues in the case and "simplify the issues for trial." *See, e.g.*, *Actelion*, 2013 WL 5524078, at *54 (deferring the start of discovery is favored where pending motion to dismiss could "narrow[ ] or outright eliminate[e] the need for discovery") (internal quotations omitted); *Mann v. Brenner*, 375 F. App'x 232, 239 (3d Cir. 2010) (recognizing that "it may be appropriate to stay discovery while evaluating a motion to dismiss where, if the motion is granted, discovery would be futile"); *Weisman v. Mediq, Inc.*, No. 95-1831, 1995 WL 273678, at *2 (E.D. Pa. May 3, 1995) ("Where a pending motion to dismiss may dispose of the entire action and where discovery is not needed to rule on such motion, the balance generally favors granting a motion to stay.") (internal citations omitted). Finally, discovery has not yet begun and no trial date has been set. *Galarza v. Whittle-Kinard*, No. 16-764, 2017 WL 2198182, at *3 (D. N.J. May 18, 2017) (Mannion, J.) (ordering stay where "[d]iscovery [wa]s truly in its infancy stage" and no trial date had been set). Every factor weighs in favor of deferring discovery pending the resolution of Teva's Motion.

Mylan itself sought (successfully) to defer discovery for precisely the same reasons in another antitrust case regarding Mylan's EpiPen product. *See Serrano v. Mylan M.V.*, No. 16-2711, ECF 79 (D. Kan. Mar. 24, 2017). As a defendant in *Serrano*, Mylan urged the court to defer the "broad and onerous fact discovery," "none [of which was] necessary to decide"

Mylan's motions to dismiss, motions that Mylan argued were "likely to eliminate entirely—or, at a minimum, significantly narrow—the scope of discovery in [that] case." *Id.* at 2. Mylan correctly noted that "requiring Defendants to undertake the broad discovery that Plaintiffs seek would be unduly expensive, burdensome, and prejudicial, particularly because all or most of that discovery is likely to be for naught." *Id*. The court in *Serrano* agreed. *See Id*. at ECF 108 (granting stay of discovery pending the resolution of the motions to dismiss). Teva respectfully submits that the Court should do the same here.

B. Mylan's Phased Discovery Should Be Denied

Mylan's proposal for an initial "Phase 1" document production also should be denied, for several reasons. Mylan proposes that Teva reproduce materials produced to Congress, the DOJ, and the FDA in connection with various past and present investigations and litigations, including many that are entirely unrelated to the issues in this case. Mylan apparently makes this proposal on the premise that these documents are purportedly "capable of production without further collection and review," but that premise is not accurate, and courts properly deny requests of exactly this type, calling for documents previously produced in one matter to be reproduced wholesale in a different matter.

1. "Cloned" Discovery is Improper. As a legal matter, "'[c]loned discovery', requesting all documents produced or received during other litigation or investigations, is irrelevant and immaterial unless the fact that particular documents were produced or received by a party is relevant to the subject matter of the instant case." *Midwest Gas Servs., Inc. v. Indiana Gas Co.*, 2000 WL 760700, at *1 (S.D. Ind. 2000). "This is because, without more, the Court cannot ascertain whether the documents requested actually relate to Plaintiffs' claims and defenses." *King Cty. v. Merrill Lynch & Co.*, No. C10-1156-RSM, 2011 WL 3438491, at *3 (W.D. Wash. Aug. 5, 2011) (internal citations omitted). Any production would require that Mylan articulate the relevant materials it seeks which would allow search

terms be run against the previously produced documents to identify responsive and relevant materials *in this case*. *Midwest Gas Servs.*, 2000 WL 760700, at *1 ("[P]laintiffs' counsel must do their own work and request the information they seek directly."); *In re Worldcom, Inc. Secs. Litig.*, 2003 WL 22953645, at *7 (S.D.N.Y. 2003) (denying request for cloned discovery because counsel must "fashion their own document requests").

Indeed, a court in another matter involving Copaxone recently denied a motion that had asked Teva to produce to private plaintiffs the entirety of what it produced to Congress on these very grounds. *Humana Inc. v. Teva Pharmaceuticals USA Inc., et al.*, No. 21-00072, ECF 68 (M.D. Fla. Oct. 19, 2021); *see also Cap. Ventures Int'l v. J.P. Morgan Mortg. Acquisition Corp.*, No. 12-10085, 2014 WL 1431124, at *1 (D. Mass. Apr. 14, 2014) (denying cloned discovery where "plaintiff indiscriminately pursues wholesale production of all testimonial materials from all employees in all cases or investigations . . . regardless of their connection to the . . . specific claims at issue here."); *Nguyen v. Raymond James & Assoc., Inc.*, No. 20-195, 2020 WL 6801874, at *3 (M.D. Fla. 2020) (denying request for "cloned" discovery because "even if some of the documents sought ultimately may be relevant to this action, the request as drafted is an overbroad request for a document dump").

2. Production Requires Prior Extensive and Time-Consuming Review. Contrary to Mylan's argument, the three categories of documents Mylan requests as Phase 1 materials cannot simply be produced without further review; to the contrary, extensive and time-consuming review would be required.

(a) *Congress*. Teva made materials available to the House subcommittee under procedures that vary substantially from the Federal Rules of Civil Procedure. *Bean LLC v. John Doe Bank*, 291 F. Supp. 3d 34, 44 (D.D.C. 2018) ("Congress's power to investigate 'is as penetrating and far-reaching as the potential power to enact and appropriate under the Constitution.'" (quoting *Eastland v. U.S. Servicemen's Fund*, 421 U.S. 491, 504

(1975)). The materials were made available to the House subcommittee in a multi-stage process with varying degrees of access and agreements regarding confidential treatment. Teva made tens of thousands of documents available to the committee staff in an electronic reading room, without redactions for relevance or other matters. The overwhelming majority of them were never requested by or submitted to the committee. At a minimum, the entire set would need to be re-reviewed to ensure no sensitive materials would be produced absent a protective order. Moreover, targeted search terms for relevance to this litigation would also need to be applied, as discussed below. Therefore, a re-review would be far from the "minimal effort" Mylan claims. Even focusing just on the subset of documents actually submitted to the subcommittee staff, they would still require review to determine whether they are appropriately responsive and to be redact as may be appropriate for production in this private litigation.

(b) *Department of Justice*. Mylan seeks all materials provided to the DOJ, whether voluntarily or pursuant to specific requests. Again, therefore, these documents were produced under rules that differ from the Federal Rules of Civil Procedure, and they would need to be re-reviewed prior to production in this matter. *Cap. Ventures Int'l v. J.P. Morgan Mortg. Acquisition Corp.*, No. 12-10085, 2014 WL 1431124, at *2 (D. Mass. Apr. 14, 2014) ("Government investigations also may be much broader than the limited subject matter of a lawsuit.").

(c) *FDA*. Mylan seeks all materials provided to the FDA, either by request or voluntarily, in connection with Teva's Citizens Petitions. Just as with the DOJ materials, the FDA documents were produced under rules that differ from the Federal Rules of Civil Procedure, and they would need to be re-reviewed prior to production in this matter.

3. Relevance and Burden. Additionally, the "Phase 1" discovery Mylan seeks is substantially overbroad, *even if* the Court were to deny Teva's Motion in its entirety. The

House investigation includes issues that have no relevance to this dispute, including for example issues of executive compensation. The DOJ materials involve documents about several matters with allegations entirely unrelated to the issues in this case. For example, one matter relates to claims under the Foreign Corrupt Practices Act about alleged conduct in Russia, which obviously have no bearing on this dispute, which Mylan concedes in its Complaint is limited any purported effects on competition in the United States.[1] Another matter involves allegations of using speaker events to bribe doctors to prescribe certain drugs, including Copaxone[2]—Mylan makes no such allegations here. As to the FDA materials, the actual Citizen Petitions Teva filed, and the FDA's responses to those petitions, are already accessible on the FDA's public websites, and Mylan does not explain why it needs more than that at this preliminary stage of proceedings.

Further, as to all three categories, counsel for Teva in this matter was not involved in reviewing or producing the documents that Mylan requests. As discussed above, the documents Mylan requests were produced under different rules and procedures, and as such any production of those documents will require counsel in this litigation to coordinate with Teva's prior counsel to first gain access to those productions, and then to act diligently and prudently to substantively review those productions and make an assessment based on that review for relevance and privilege. Only after those steps are completed will Teva be able to eventually produce those documents, if any, that are nonprivileged and relevant to Mylan's claims in this case.

[1] One of the Requests for Production Mylan already served explicitly seeks "[a]ll documents and case materials in and/or produced in the criminal case captioned *United States v. Teva LLC (Russia)*, No. 1:16-cv-20968 (S.D. Fla.). This Request includes, but is not limited to, any documents produced outside a Court-supervised discovery process (*e.g.*, documents provided in the course of plea negotiations)."

[2] Mylan's Request for Productions seeks "[a]ll documents and case materials in and/or produced in the case captioned *United States et al. ex. rel. Charles Arnstein and Hossam Sanousy v. Teva Pharmaceuticals USA Inc. et al.*, No. 1:13-cv-03702 (S.D.N.Y.)."

C. Certain Discovery-Related Tasks Should Proceed Now

Nevertheless, to advance this litigation in an appropriate manner without imposing undue burdens on Teva, Mylan, or the Court, Teva agrees that it would be appropriate for the parties to undertake initial discovery-related tasks that are not highly burdensome while its Motion is pending. Consistent with the Court's prior order, Teva will serve the disclosures required by Fed. R. Civ. P. 26(a)(1). Teva also agrees that, prior to the resolution of its Motion, the parties should negotiate a confidentiality order and protocol for electronically-stored information.

For the avoidance of doubt, while the parties present a joint proposal below concerning the number of interrogatories and requests for admission, it is Teva's position that such discovery should be deferred until after Teva's motion to dismiss is decided.

(c) Number of Interrogatories and Requests for Admission:

The Parties agree that each party may serve a maximum of twenty-five (25) Interrogatories, in accordance with FRCP 33(a)(1). Notwithstanding the foregoing, the Parties reserve the right to seek leave of the Court to increase the number of Interrogatories to be served. The Parties agree that there should be no limits on the number of requests for admission that any party may serve.

(d) Number of Depositions:

(1) Plaintiff's Position

Both Parties may take a total of twenty (20) fact depositions. Notwithstanding the foregoing, the Parties reserve the right to seek leave of the Court to increase the number of fact depositions to be taken. Each Rule 30(b)(6) deposition counts against the per-side fact deposition cap. Any Rule 30(b)(6) deposition of a named party noticed by Plaintiff or Defendant counts as one (1) deposition no matter the number of witnesses designated to testify, unless the deposition exceeds 7 hours. In the event that a Rule 30(b)(6) deposition

exceeds 7 hours, the additional hours shall count as an additional deposition or the pro rata portion of an additional deposition (e.g., if a Rule 30(b)(6) deposition lasts 14 hours, it shall count as 2 depositions out of the 20 party depositions allocated per party; if a Rule 30(b)(6) deposition lasts 10.5 hours, it shall count as $1^1/_2$ depositions out of the 20 party depositions allocated per party). If a deposition requires a foreign language translator, the proposed timing should be increased by 2 times. Subject to the per-party fact deposition cap, the Parties are not precluded from seeking the deposition of a Rule 30(b)(6) designee in their individual capacity. A non-party deposition will not count as one deposition against the per-party fact deposition cap.

(2) Defendants' Position

To the extent Teva's Motion is denied in its entirety, each Party would be permitted to take a total of fifteen (15) fact depositions of the other Party, with depositions of former employees counting as depositions of a Party, and using the Rule 30(b)(6) counting mechanism described in Section 5(d)(1), and that each Party additionally would be permitted to take up to ten (10) depositions of non-parties. However, to the extent Teva's Motion is granted in part, Teva submits that it may be appropriate to impose further restrictions on the number of depositions allowed to reflect any narrowing of the issues in the case. Thus, Teva submits it is premature to increase the default number of depositions at this time, and the parties can, should it be necessary, meet and confer and approach the Court following a decision on Teva's Motion to adjust the permitted number of depositions.

6. (e)-(j) Case Schedule

For ease of reference, the Parties' proposed deadlines are included below. This includes all the information requested from 6(e)-6(j). Please note that the deadline for motions to amend or to add parties (6(g)) is premature and should be determined after the pending motion to dismiss is resolved.

As detailed above, Teva submits that discovery should be deferred pending the resolution of its Motion. Therefore, Teva's proposed case schedule largely includes dates to be calculated based on the date the Court rules on Teva's Motion and such ruling does not include a complete dismissal.

Event	**Plaintiff's Proposal**	**Defendants' Proposal**
Rule 26(a)(1) Initial Disclosures served	February 8, 2022	March 4, 2022
Initial Scheduling Conference	February 22, 2022	February 22, 2022
Deadline for submission of proposed Discovery Confidentiality Order and Electronically Stored Information Protocol	March 8, 2022	April 30, 2022
Deadline for substantial completion of production of Phase 1 discovery materials	April 22, 2022	Not applicable; phased discovery is not appropriate here.
All Parties serve first request for production of documents for Phase 2	April 22, 2022	30 days from the Court's ruling on the Motion
Deadline for submitting joint or separate proposal(s) for Search Protocols for Electronic Documents	May 23, 2022	60 days from the Court's ruling on the Motion
Deadline for substantial completion of production of documents responsive to all Phase 2 requests for production served on or before June 30, 2022	September 23, 2022	15 months from the Court's ruling on the Motion
Fact discovery closes; all discovery requests must be served to be answerable by this date	April 24, 2023	18 months from Court's ruling on the Motion
Deadline for the party with the burden of proof on an issue to serve its expert report(s) on that issue, with the dates for expert depositions to be provided at the time of filing	June 30, 2023	8 weeks after the close of fact discovery
Deadline for the Parties to serve responsive expert reports, with the dates for expert depositions to be provided at the time of service	July 31, 2023	8 weeks after the deadline to serve opening expert reports
Deadline for the Parties to serve rebuttal expert reports, with the dates for expert depositions to be provided at the time of service	August 31, 2023	4 weeks after the deadline to serve responsive expert reports

Expert discovery closes	November 1, 2023	2 months after deadline to serve rebuttal expert reports
Last date to file Rule 56 dispositive motions	December 1, 2023	8 weeks after the close of expert discovery
Final Pretrial Conference	At the Court's convenience	At the Court's convenience
Trial	At the Court's convenience	At the Court's convenience

(k) Special Discovery Procedures

(1) The Parties have agreed that drafts of expert reports or declarations and notes, written communications, and other types of preliminary work created or generated by or for experts or their staff (unless such notes are generated while testifying) are exempt from discovery. Communications between and among (a) experts, including their staff, and outside counsel, (b) experts, including their staff, and other experts or consultants and their respective staff, and/or (c) experts and their respective staff shall not be discoverable unless the expert specifically relied upon any such communications as a basis for any of his or her ultimate opinions or reports. Suggestions from outside counsel regarding revisions to the form of the expert's report or additional support for the expert's ultimate opinions are examples of communications that are protected from discovery under this Order.

(2) The Parties anticipate that a Discovery Confidentiality Order governing the treatment of confidential information will be required and that the Court will be asked to adopt it. The Parties agree to meet and confer and submit a proposed Discovery Confidentiality Order for the Court's consideration.

(3) The Parties are prepared to engage in reasonable electronic discovery in response to discovery requests. The Parties agree to meet and confer and submit a proposed Electronically Stored Information Protocol for the Court's consideration.

(4) The Parties agree that, except where infeasible, they shall serve all pleadings, discovery requests, and discovery responses by electronic mail. Service of discovery requests will be deemed to have been made on the day the electronic mail is sent. Service of pleadings and discovery responses will be deemed to have been made on the day electronic mail is sent by the sender, based on the time zone of the District Court.

(l) Pretrial Conference

Mylan proposes that a pretrial conference should be set by the Court, at its convenience according to Mylan's proposal. Teva submits that it is premature to set a pretrial conference in light of Teva's pending Motion to Dismiss.

(m) Jury Trial

In its Complaint, Mylan demanded a trial by jury pursuant to Rule 38 of the Federal Rules of Civil Procedure.

(n) Trial Date

It is Mylan's position that a trial date should be set by the Court, at its convenience according to Mylan's proposal. Teva submits that it is premature to set a trial date in light of Teva's pending Motion to Dismiss.

7. Anticipated Discovery Problems

No discovery problems are anticipated at this time.

8. Special Discovery Needs

The Parties anticipate the need to videotape many, if not all, depositions. Mylan also anticipates that discovery may need to be obtained from entities overseas.

9. Alternative Dispute Resolution Procedures

The Parties are amenable to jointly agreed upon mediation provided Parties agree on a Special Master to facilitate resolution or discussion.

10. Bifurcation

The Parties do not believe this case is appropriate for bifurcation.

11. Trial Conducted by Magistrate Judge

The Parties do not consent to the trial being conducted by a Magistrate Judge.

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